Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The comparison effects of intraarticular injection opioids (morphine, tramadole, methadone and pethidine) on postoperative pain relief after knee surgery (anterior cruciate ligament reconstruction)

Protocol summary

Summary

The aim of this study is to compare analgesic effect of intraarticular injection of opiodes after knee surgery. This study will be done as a double-blind randomized controlled clinical trial on 150 patients. Inclusion criteria are: ASAI or ASAII class of American Society of Anesthesiologist; Age range of 18-65 years old; Tolerance to general anesthesia and sign of informed consent. Exclusion criteria are: history of allergic reaction to administered drugs; history of drug abuse; history of chronic pain; consumption of MAOI agent; using preoperative opioids or other analgesic drugs . 150 patients will be recruited in five groups randomly. All of them receive an intraarticular injection contained 9.5 ml bupivacain with 1:200,000 epinephrine, at the end of surgery in a 10ml syringe. The remainder of syringe is filled with one of the below solution: Group I, 5 mg methadone; Group II, 5 mg morphine; Group III, 37.5 mg pethidine; Group IV, 100 mg tramadol; Group V, 0.5 ml normal saline. Then patients receive analgesic based on their needs every 4 hours. The patients need to analgesics during first 12 hours (every 4 hours) after hospitalization, and pain score based on VSA are measured and recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201106102341N4**
Registration date: **2011-09-04, 1390/06/13**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-09-04, 1390/06/13

Registrant information

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Hamidreza Arti

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Shahrekord and Ahvaz Uniuversity Of Medical Sciences

Expected recruitment start date

2005-03-21, 1384/01/01

Expected recruitment end date

2007-03-21, 1386/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison effects of intraarticular injection opioids (morphine, tramadole, methadone and pethidine) on postoperative pain relief after knee surgery (anterior cruciate ligament reconstruction)

Public title

The comparison effects of intraarticular injection opioids (morphine, tramadole, methadone and pethidine) on postoperative pain relief after knee surgery (anterior cruciate ligament reconstruction)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: candidate of ruptured knee ACL reconstruction ; ASAI or ASAII class of American society of Anesthesiologist; Age between 18- 65 years old; Tolerance to general anesthesia and sign of informed consents. Exclusion criteria: history of allergic reaction to administered drugs in this study; history of drug abuse; history of chronic pain; consumption of MAOI agent ; using preoperative opioids or other analgesic drugs.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahrekord University Of Medical Sciences

Street address

Kashani Bulvard

City

Shahrekord

Postal code

8815713470

Approval date

2006-05-22, 1385/03/01

Ethics committee reference number

3-2-58

Health conditions studied

1

Description of health condition studied

pain after knee anterior cruciate ligament reconstruction

ICD-10 code

M24.2

ICD-10 code description

Instability secondary to old ligament injury

Primary outcomes

1

Description

pain after knee anterior cruciate ligament reconstruction

Timepoint

every 4 hours

Method of measurement

visual analouge score

Secondary outcomes

1

Description

pain relief and reduction of need to analgesics

Timepoint

every 4 hours

Method of measurement

visual analouge score

Intervention groups

1

Description

Morphine group receives 0.5% bupivacaine with 1:200,000 epinephrine and 5mg morphine

Category

Treatment - Drugs

2

Description

Methadone group receives 0.5% bupivacaine with 1:200,000 epinephrine and 5mg methadone

Category

Treatment - Drugs

3

Description

Pethidine group receives 0.5% bupivacaine with 1:200,000 epinephrine and 37.5 mg Pethidine

Category

Treatment - Drugs

4

Description

Tramadol group receives 0.5% bupivacaine with 1:200,000 epinephrine and 100 mg Tramadol.

Category

Treatment - Drugs

5

Description
Control group receives 0.5% bupivacaine with 1:200,000 epinephrine 0.5 ml normal saline.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Kashani Hospital of Shahrekord
Full name of responsible person
Dr. Hamidreza Arti
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Varzesh St.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahrekord university of Medical Sciences/ Ahvaz Jundishapour University of Medical Sciences
Full name of responsible person
Dr. Mahmood Mobasheri
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Kashani Bulvard, Vice Chanceller for Research of Shahrekord University of Medical Sciences
City
Shahrekord
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahrekord university of Medical Sciences/ Ahvaz Jundishapour University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty